## DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

## DRUGS FOR HUMAN USE\*

2722. Misbranding of Lemel. U. S. v. 300 Dozen Packages \* \* \* (F. D. C. No. 26006. Sample No. 2748–K.)

LIBEL FILED: November 4, 1948, District of Columbia.

ALLEGED SHIPMENT: On or about October 28, 1948, by the Serutan Co., from Newark, N. J.

PRODUCT: 300 dozen packages of Lemel at Washington, D. C.

Label, In Part: (Package) "Lemel 20 Packets Each Packet Contains Vitamin C Equal to 7 Lemons (Av.) Ingredients: Dextrose, lemon powder, oil of lemon, oil of lime, potassium bitartrate and tartaric acid (from grapes), potassium citrate, ascorbic acid, thiamin hydrochloride, riboflavin, niacin, niacinamide, potassium phosphate, magnesium carbonate, calcium carbonate. Lo-Calory Food Corp., New York, N. Y. Each Lemel Packet Contains: Vitamin C... 150 mgs. (5 MDR), Vitamin B<sub>1</sub>... 5 mgs. (5 MDR), Riboflavin... 2 mgs. (1 MDR), Niacin... 25 mgs.\*, Niacinamide... 25 mgs.\* MDR-Minimum Daily Requirement. \*MDR not established."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements in a leaflet enclosed in each package of the product were false and misleading: "Lemonade has long been used in colds, grippe and flu. Many who suffer from joint aches and pains are accustomed to taking the juice of 1 or more lemons as a morning drink. Today, in Lemel you can get the Vitamin C value of the juice of 7 Average Lemons \* \* \* Use Lemel regularly and faithfully." The statements represented and suggested that the article was effective in the treatment of colds, grippe, flu, and joint aches and pains. The article was not effective in the treatment of such diseases, symptoms, and conditions. The article was alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods, No. 14293.

DISPOSITION: December 15, 1948. Lo-Calory Food Corp., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered released under bond for relabeling under the supervision of the Food and Drug Administration.

2723. Misbranding of lemon juice. U. S. v. 22 Cases \* \* \* (and 1 other seizure action). (F. D. C. Nos. 26092, 26093. Sample Nos. 18293-K, 18294-K.)

LIBELS FILED: November 24, 1948, Northern District of Ohio.

ALLEGED SHIPMENT: On or about September 1, 1948, by the Puritan Company of America, from Chicago, Ill.

PRODUCT: 77 cases, each containing 24 1-pint bottles, of lemon juice at Cleveland, Ohio.

LABEL, IN PART: "Realemon Brand 100% Real California Lemon Juice."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statements "For Health and Regularity \* \* \* For Fighting or Breaking Colds" were false and misleading since use of the product would not promote health and regularity, and the product would not be effective in the treatment of colds.

<sup>\*</sup>See also Nos. 2715-2717, 2719-2721.

The product was alleged also to be adulterated and misbranded under the provisions of the law applicable to foods.

DISPOSITION: January 12, 1949. Default decrees of condemnation and destruction.

2724. Misbranding of Rybutol Gelucaps. U. S. v. 124 Dozen Bottles, etc. (F. D. C. No. 26636. Sample No. 51252-K.)

LIBEL FILED: March 7, 1949, Southern District of Ohio.

ALLEGED SHIPMENT: By the Vitamin Corporation of America, from Newark, N. J. The product was shipped on or about January 11, 1949, and the labeling of the article, with the exception of certain newspaper clippings, was shipped on or about January 10 and February 12, 1949.

PRODUCT: 70 dozen bottles, each containing 100 capsules, and 54 dozen bottles, each containing 50 capsules, of *Rybutol Gelucaps* at Cincinnati, Ohio, in the possession of the Dow Drug Co. Warehouse, together with a number of leaflets entitled "Ask Your Doctor" and a number of Cincinnati newspaper clippings entitled "Why does your Doctor Prescribe Rybutol?" The newspaper clippings were displayed with the product in the retail stores of the Dow Drug Co. Some of the clippings were pasted in the windows of the stores or were used as streamers, hanging from a wire in the rear of the stores in close proximity to the goods.

LABEL, IN PART: "Rybutol High Blend Natural Vitamin B Complex. Each Gelucap Contains the Whole Natural Vitamin B Complex Fortified."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the newspaper clippings were misleading. These statements represented and suggested that the article was effective to correct and prevent nervousness, mental depression, atrophy, fatigue, loss of appetite, allergies, dental decay, gum infections, excessive weight, anemias, paleness of the skin, loss of energy, palpitation, run-down feeling, listlessness, improper food assimilation, faulty elimination, and birth of anemic infants. The article was not effective for such purposes. The article was misbranded while held for sale after shipment in interstate commerce by reason of the above statements in its labeling.

Further misbranding, Section 502 (a), the statement "Hy-Blend Natural Vitamin B Complex" appearing on the label of the article, in a leaflet entitled "Ask Your Doctor," and in the newspaper clippings, was false and misleading as applied to an article which was not a high potency natural vitamin B complex but a mixture of some of the members of the vitamin B complex in synthetic form, an iron salt, vitamin C, and nutritionally inconsequential amounts of natural sources of the B complex.

The article was alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

Disposition: March 14, 1949. The Vitamin Corporation of America, claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond for relabeling under the supervision of the Federal Security Agency.

2725. Misbranding of S-V-S<sup>X</sup> Vitamin Tablets. U. S. v. 26 Boxes \* \* \*. (F. D. C. No. 26655. Sample No. 40314–K.)

LIBEL FILED: March 14, 1949, District of Maryland.

ALLEGED SHIPMENT: On or about July 23, 1948, by the Pell-Ma Medicine Co., from Los Angeles, Calif.